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July 22, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers LN, RM 1061
Rockville, MD 20857 - 0003

Re: Docket No. 98N - 1265 (MOU)

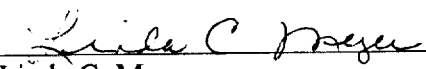
Reference is made to your Memorandum of Understanding (MOU) and to the FDA Modernization Act of 1997, Section 503 A. Apparently the MOU restricts interstate distribution of compounded drugs even though these have been prescribed by a fully qualified physician for a patient who is in full agreement, finds the product(s) extremely helpful and is unable to obtain them locally. **Why should an individual's state of residence affect their ability to obtain drugs prescribed by their physician?**

This restriction substantially deviates from the purpose of the FDA. It has nothing to do with safety. **It is control of our rights as free people to make our own choices with regard to our health in consultation with our physician.**

We are also very concerned that the compounding Section 503 A of the Modernization Act restricts communication between pharmacists and physicians in the case of compounded drugs. It seems we have a double standard here. The major drug companies are providing doctors with free samples and free seminars about their products all the time. In addition, does not the First Amendment to the U.S. Constitution protect freedom of speech ie communication between the pharmacist and doctor? The doctor doesn't have to take the pharmacist's advice and neither does the patient! If the first amendment can be interpreted to allow pornography then it certainly protects the right of a pharmacist to talk to a physician in the best interests of the patient.

In conclusion, we ask that the MOU and the Compounding Section 503 A of the Modernization Act be amended or repealed in part to address the concerns we have outlined above.

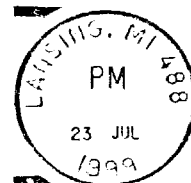

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